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14. ABSTRACT This study seeks to determine whether Internet-Based Expressive Writing (IB-EW), a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms and improve functioning among veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations, its efficacy in combat veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also attempt to identify individual difference characteristics related to the efficacy of the treatment, to indicate who is most likely to benefit from the treatment in order to inform treatment implementation strategies.								
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Please note that we have submitted a request for a one-year no-cost extension that is currently under consideration. We are therefore submitting this report as an annual report rather than a final report.

INTRODUCTION:

This study seeks to determine whether Internet-Based Expressive Writing (IB-EW)¹, a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms² and improve functioning³⁻⁵ among Veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations⁶, its efficacy in combat Veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed Veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also determine who is most likely to benefit from Internet-Based Expressive Writing in order to inform treatment implementation strategies.

BODY:

This section of the Annual Report is organized according to the study's Statement of Work (SOW), which appears throughout this section in underlined font as well as in Appendix A.

Milestone 1: Preparing for Implementation (Month 1-12)

With the exception of certain ongoing tasks (e.g., continuing IRB review), all Milestone 1 tasks are now completed.

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)

Ongoing.

► Initial human subjects protection approvals and annual continuing review approvals were obtained in past reporting periods. **During the current reporting period, we obtained VA IRB continuing review approval in March 2012. We submitted DoD HRPO continuing review materials in September 2012.**

- VA Central Office approval to obtain real SSNs and address information (Month 6-9)

Completed in Year 1.

- VA Central Office approval to access OIF/OEF Roster (Month 6-9)

Completed in Years 1 and 2.

- OMB Exemption for Research (Month 6)

Completed in Year 1.

- Web Ops review of project web application and posting of application on the VA Web Ops server (Month 6-9).

Completed in Years 1 and 2.

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

Completed during the current reporting period (Year 4).

- We obtained the final two of four quarterly $n=5,000$ roster pulls with address information from VA Environmental Epidemiology Services' OEF-OIF roster during the current reporting period (September 2011 and December 2011).

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Completed in Year 1.

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

Completed in Years 2 and 3.

Milestone 2: Data Collection (Month 13-36)

With the exception of ongoing tasks related to data collection for follow-up study sessions, all Milestone 2 tasks are now complete. Recruitment, enrollment, baseline data collection, and the online delivery of study interventions and writing-session assessments are now complete; follow-up data are still being collected.

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Completed during the current reporting period (Year 4).

- We completed participant recruitment in June 2012, having sent out recruitment materials to $n=18,483$ Veterans over 12 months (**approximately 1,500 per month**). We purposefully exceeded our original target recruitment numbers (after obtaining IRB approval) based on pilot work done in Year 3 that suggested our recruitment response rates would be lower than originally expected.

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Completed during the current reporting period (Year 4).

- We randomized a total of $n=1,438$ Veterans into the study. Because approximately 10% of randomized participants did not complete any online study sessions, we purposefully exceeded our original target of $n=1,152$ randomized participants after obtaining IRB approval to do so. Participants were randomized during a 13-month period from July 2011 to August 2012, for an **average of $n=111$ per month**.

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Completed during the current reporting period (Year 4).

- Of the $n=1,438$ participants who were randomized into the study, $n=1,363$ (95%) set a session schedule on the study website, received a copy of their schedule by mail and email, and were informed that they could log-in to the study website to view/revise their session schedule at any time. The remaining $n=75$ did not set a session schedule on the study website as instructed and therefore did not receive a session schedule.

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Completed during the current reporting period (Year 4).

- Of the $n=1,438$ randomized participants, $n=1,275$ (89%) completed their baseline study session online and were eligible for future study sessions, slightly exceeding

the $n=1,152$ target number of baseline completers on which power analyses for planned study analyses was based. Baseline sessions were completed during a 13-month period from July 2011 to August 2012, for an **average of 98 per month**.

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Completed during the current reporting period (Year 4).

► Of the $n=1,275$ participants who completed the baseline session and were therefore eligible to continue with the study, $n=1,005$ had been randomized to one of the writing conditions (EW=503, CW=502). Of these, $n=861$ (86%) completed at least one online writing session and $n=553$ (55%) completed all four writing sessions.

Writing sessions were completed during a 13-month period from July 2011 to August 2012, for an **average of $n=66$ participants writing per month**.

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Completed during the current reporting period (Year 4).

► All writing samples submitted online were reviewed to assess for risk of harm to self or others. Of the $n=861$ participants who completed a writing sample online, writing samples submitted by $n=9$ were deemed to possibly confer elevated safety risk and referred to the study's independent Risk Assessor for further assessment. Of these, $n=7$ yielded non-emergency outreach and resource referrals and $n=2$ were deemed not to require any further response. None required emergency outreach.

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Ongoing.

► Participants receive a reminder postcard 2 weeks before their scheduled 3-month follow-up session and a reminder email 1-3 days before the session. We anticipate that the final 3-month follow-up session will be completed in November 2012.

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month* follow up assessment online (Month 22-36). (*As documented in our Year 3 annual report, the 9-month follow-up assessment occasion was changed to 6-month follow-up).

Ongoing.

► Participants receive a reminder postcard 2 weeks before their scheduled 6-month follow-up session and a reminder email 1-3 days before the session. We anticipate that the final 6-month follow-up session will be completed in February 2013.

Task 13: Contact of participants who fail to complete 3-month and/or 9-month* follow up assessments as scheduled (Month 16-36). (*The 9-month follow-up assessment occasion was changed to 6-month follow-up).

Ongoing.

► 3-month and 6-month follow-up sessions are ongoing. All participants who miss a follow-up assessment session receive outreach according to established study procedures, including email, postcard, and/or telephone reminders. Participants who are not responsive to missed follow-up session outreach receive a paper-and-pencil copy of the assessment measures in the mail.

Milestone 3: Data Preparation (Month 37-39)

We began addressing Milestone 3 tasks during the current reporting period. Baseline and writing session data collection concluded in August 2012. Baseline data, as well as roster and eligibility survey data, have been prepared for study analyses, while writing session data preparation is underway. Follow-up session data are still being collected and VA administrative service-use data have not yet been extracted. All study data will be cleaned, merged, and ready for analysis in the spring of 2013.

Task 14: Clean and merge assessments for data analysis (Month 37-38).

In process.

- Recruitment, administrative roster, and eligibility survey data have been cleaned and merged for data analysis. Baseline and writing session data are in the process of being cleaned and will be merged with other data in the fall of 2012. We anticipate completing data collection for 3-month follow-up in November 2012 and for 6-month follow-up in February 2013; follow-up data will be cleaned and merged with other study data in spring 2013.

Task 15: Upload participant's essays into ATLAS.ti for coding (Month 37-40)

Not completed.

- Writing session data is in the process of being cleaned and will be loaded into Atlas.ti for qualitative coding in the fall of 2012.

Task 16: Extract VA service use data for all participants from VA administrative databases; clean and merge data (Month 39)

Product: Data sets ready for analysis

Not completed.

- We anticipate completing VA administrative service use data extraction in the winter of 2012.

Milestone 4: Data Analysis, Dissemination and Products (Month 40-48)

Primary data analysis, dissemination of findings, and product completion were not yet underway as of the end of the current reporting period. We have completed data collection for the baseline and writing phases of the study and have datasets for eligibility survey data and roster data, but are still collecting 3- and 6-month follow-up session data and have not yet extracted VA administrative service use data. The study's primary statistical analyses will be conducted in the spring and summer of 2013 after follow-up data are collected, administrative data are extracted, and all datasets are cleaned and merged. Nevertheless, data analysis and preparation of products such as manuscripts based on baseline, eligibility, and roster data are currently underway. Primary data analysis, dissemination, and product completion, including Tasks 17-22 below, will be completed during Year 5 of the study (i.e., during the one-year no-cost extension we have requested).

Task 17: Conduct statistical analyses to address primary hypotheses (Month 40-42)

Product: Tested web-based intervention for improving outcomes among OIF/OEF veterans with post-deployment reintegration problems that can be used throughout VA for very little expense.

Task 18: Code participant essays (Month 40-43)

Task 19: Analyze coded essays (Month 43-45)

Product: Catalogue of post-deployment reintegration challenges and needs from the perspective of OIF/OEF veterans that can be used to inform other interventions

Task 20: Dissemination and implementation plan meeting in Minneapolis (Month 43)

Task 21: Conduct statistical analyses to address secondary and exploratory hypotheses (Month 43-45)

Task 22: Dissemination Activities/Products and Deliverables (Month 46-48)

- Manuscript preparation (Product)
- Report writing (Product)
- Executive summary preparation and distribution to DoD and VA stakeholders (Product)
- Presentations to DoD and VA stakeholders (Product)
- Presentations at scientific meetings (Product)

KEY RESEARCH ACCOMPLISHMENTS:

Administrative

1. We continued to meet regularly as a project team to coordinate project activities, including meeting to plan for the transition from the Data Collection (Statement of Work Milestone 2) to the Data Preparation (SOW Milestone 3) and Data Analysis, Dissemination, And Publication (SOW Milestone 4) stages of the study.
2. New study staff were added to the study protocol to facilitate study implementation.
3. Per the study's IRB-approved Safety Manual, the study coordinator read all writing samples that were submitted online to assess for safety risk and referred participants to the study's independent risk assessor as appropriate.
4. No substantial procedural changes were submitted to IRB during the current reporting period; a small number of minor amendments were approved (e.g., increasing maximum enrollment size to compensate for participants who enroll in the study but do not complete any study sessions).
5. We submitted VA IRB continuing review materials in January 2012 and received continuing review approval in March 2012. We submitted DoD HRPO continuing review materials in September 2012.
6. We met with the study's CDMRP Science Officer, Dr. Shui-Lin Niu, by conference call in January 2012 to discuss the study's timeline and our request for a no-cost extension; a no-cost extension request submitted in March 2012 remains in process.

Recruitment and Enrollment

7. We completed participant recruitment and enrollment. We had IRB approval to contact up to 20,000 individuals for recruitment, and our original target for enrollment was $n=1,152$ enrolled/providing baseline data. However, because approximately 10% of enrolled participants did not complete any study sessions, we obtained IRB approval to increase our total enrollment to up to $n=1,550$. We stopped recruitment mailings after sending materials to $n=18,483$ individuals, when it became evident that we had sent enough recruitment materials to reach our enrollment and baseline session completion goals. After providing a reasonable window of opportunity for all contacted individuals to enroll if requested and eligible, we closed the study to new enrollment in July 2012, having enrolled a total of $n=1,438$ participants.
8. See Appendix B for a summary of participant recruitment, enrollment, and session completion rates.

Data Collection and Delivery of Online Intervention

9. Baseline data collection is now complete. Of $n=1,438$ enrolled participants, $n=1,275$ (89%) completed an online baseline assessment session. Completing this assessment session was required for continuation in the study.
10. Appendix C contains preliminary summary statistics for assessment measures administered at baseline.
11. Writing session data collection and delivery of online writing interventions are now complete. Of the $n=1,149$ participants who were randomized into a writing condition, $n=1005$ ($n=503$ EW, $n=502$ CW) completed their baseline assessment session and were eligible to complete their online writing sessions. Of these, $n=861$ (86%) completed at least one writing session, including $n=421$ EW and $n=440$ CW.
12. Data collection for 3-month follow-up is ongoing. We have collected data from $n=957$ participants to date, including $n=738$ who completed the session online and $n=219$ who completed it by paper-and-pencil mailing after missing their session online. We estimate that an additional $n=110$ will provide 3-month follow-up data by the end of November 2013, when we anticipate this phase of data collection to be complete.
13. Data collection for 6-month follow-up is still ongoing, as well. We have collected data from $n=655$ participants to date, including $n=538$ who completed the session online and $n=117$ who completed it by paper-and-pencil mailing after missing their session online. We estimate that an additional $n=370$ will provide 6-month follow-up data by the end of February 2013, when we expect to complete all data collection.

Participant Tracking and Outreach

14. We implemented standard tracking and outreach procedures, including mail, email, and phone contact per the study protocol for new participant recruitment, eligibility notification, study enrollment, session scheduling, upcoming session reminders, missed session reminders, and writing sample requests.
15. We referred unreachable participants to the University of Minnesota Health Survey Research Center (HSRC) to identify updated contact information and used this information to re-initiate recruitment or other outreach procedures as appropriate.
16. We implemented non-emergency outreach in consultation with the study's independent risk assessor for $n=7$ participants whose writing samples had indicated elevated risk.
17. We maintained a toll-free phone number for participants to reach us and responded as needed to participant comments and inquiries.

Data Management

18. We have cleaned and prepared recruitment response data for reporting and analytic purposes (e.g., assigned each participant into one of several mutually-exclusive recruitment outcome categories).
19. We have cleaned and prepared eligibility survey data for analysis.
20. We have extracted baseline assessment data from Web Ops servers and are in the process of preparing these data for analysis (e.g., creating scale scores from raw item-level data).
21. We have merged administrative roster data with eligibility survey data.
22. We are in the process of cleaning and preparing baseline and writing session data for analysis, including baseline assessment measures, qualitative writing samples, and quantitative pre- and post-writing data collected during online writing sessions.

23. We have conducted preliminary qualitative writing sample reviews, primarily focusing on the identification of qualitative reintegration themes.
24. We have scanned and cleaned all paper-and-pencil follow-up surveys returned by study participants and will continue to do so as they arrive. When the 3- and 6-month session phases end in November 2012 and February 2013, respectively, online data will be merged with the paper-and-pencil survey data, and collectively these data will be merged with other study data for analysis.
25. We have compiled various cost-effectiveness, implementation, and tracking-related data for analysis and dissemination to key stakeholders.

Technical Issue Navigation

26. Upon investigating participant complaints regarding technical issues in late October 2011, we learned that VA Web Ops, which maintains the servers that house our study website, had migrated our website to a new and incompatible server environment on October 25, 2011 without notifying us and that an adequate fix was not immediately available. As a result, we temporarily shut down the secure log-in portion of our website from November 4, 2011 until November 29, 2011, when the problem was corrected.
27. During the website shutdown, we suspended new recruitment mailings and enrollment of new participants, obtained IRB approval for a set of temporary outreach procedures, and implemented those procedures with affected participants. All participants who were scheduled for an online session during that time were notified of the website shutdown, and those scheduled for a 3-month follow-up assessment were sent paper-and-pencil copies of the measures to complete off-line. Following the website shutdown, additional outreach was implemented to notify enrolled participants of the problem and inform them that the website was fully operational again.
28. The website shutdown directly affected n=118 participants who were unable to complete one or more online sessions as scheduled due to the website problems. This included n=27 participants who missed scheduled baseline and/or writing sessions, some of whom (n=5) returned to the website after the shutdown to complete them. As well, n=91 participants were unable to complete their 3-month follow-up session online as scheduled due to the website problems. Of these, most (n=77) ultimately provided 3-month follow-up data, either through alternate paper-and-pencil procedures we established (n=63) or by returning to the website after it re-opened (n=14).
29. Following the website shutdown, we increased the size of each of our remaining weekly recruitment mailings to compensate for the missed weeks of mailing to ensure we completed recruitment and enrollment on schedule.
30. It appears that the technical problems and resulting website shutdown did not affect overall study progress. For example, although participants who were scheduled to complete online 3-month follow-up sessions during the shutdown were unable to do so on our website at that time, we were able to attain a 3-month follow-up completion rate for these participants (77/91, or 84%) that matched the completion rate for the rest of the sample to date (880/1,050, or 84%). As well, these participants completed their subsequent 6-month follow-up assessment session at a rate (71/91, or 78%) that is comparable to the rate for the rest of the sample (584/724, or 81%), suggesting that our website problems did not cause these participants to disengage from the study.

REPORTABLE OUTCOMES:

None.

CONCLUSION:

In Year 4, we implemented study recruitment, enrollment, and baseline and follow-up data collection procedures, slightly exceeding our target number of enrollees and baseline assessment completers. Recruitment and enrollment are now complete, as are the collection of baseline assessment data and the implementation of online study interventions and associated writing session data collection. Data collection for 3-month follow-up assessments will be complete in November 2012, and for 6-month follow-up in February 2013. We overcame a significant technical challenge in the fall of 2011 that required us to temporarily suspend recruitment, enrollment, and online data collection procedures due to problems with the servers housing our study website. We have begun data cleaning and preparation for analyses and will continue to do so as follow-up session data are completed. We have requested a one-year no-cost extension and will complete remaining Statement of Work tasks (e.g., data analysis, dissemination of findings) in the coming year.

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Appendix A – Statement of Work

Milestone 1: Preparing for Implementation (Month 1-12)

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)
- VA Central Office approval to obtain real SSNs and address information (Month 6-9)
- VA Central Office approval to access OIF/OEF Roster (Month 6-9)
- OMB Exemption for Research (Month 6)
- WebOps review of project web application and posting of application on the VA WebOps server (Month 6-9).

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

Milestone 2: Data Collection (Month 13-36)

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

Milestone 3: Data Preparation (Month 37-39)

Task 14: Clean and merge assessments for data analysis (Month 37-38).

Task 15: Upload participant's essays into ATLAS.ti for coding (Month 37-40)

Task 16: Extract VA service use data for all participants from VA administrative databases; clean and merge data (Month 39)

Product: Data sets ready for analysis

Milestone 4: Data Analysis, Dissemination and Products (Month 40-48)

Task 17: Conduct statistical analyses to address primary hypotheses (Month 40-42)

Product: Tested web-based intervention for improving outcomes among OIF/OEF veterans with post-deployment reintegration problems that can be used throughout VA for very little expense.

Task 18: Code participant essays (Month 40-43)

Task 19: Analyze coded essays (Month 43-45)

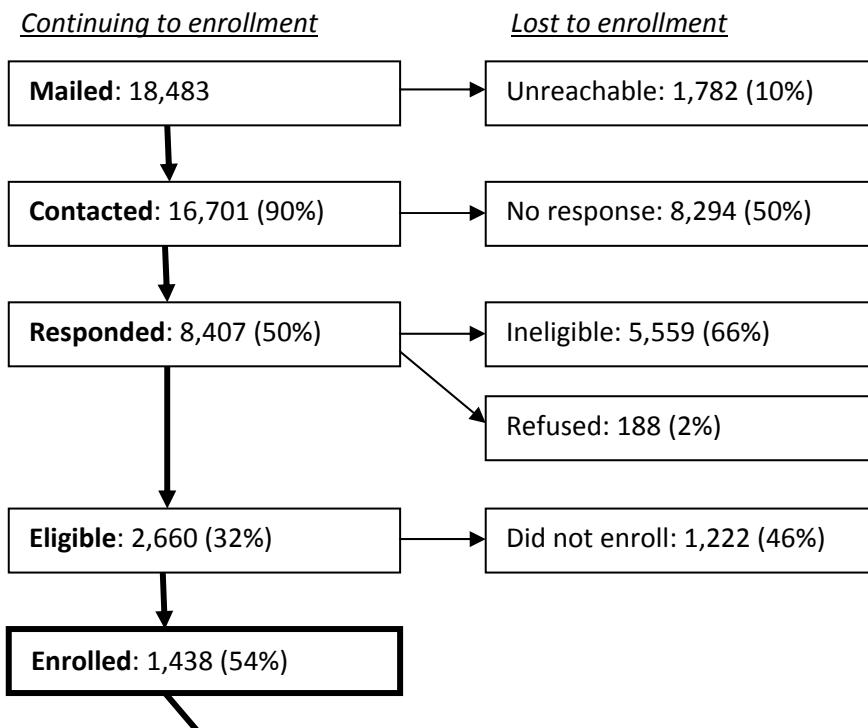
Product: Catalogue of post-deployment reintegration challenges and needs from the perspective of OIF/OEF veterans that can be used to inform other interventions

Task 20: Dissemination and implementation plan meeting in Minneapolis (Month 43)

Task 21: Conduct statistical analyses to address secondary and exploratory hypotheses
(Month 43-45)

Task 22: Dissemination Activities/Products and Deliverables (Month 46-48)

- Manuscript preparation (Product)
- Report writing (Product)
- Executive summary preparation and distribution to DoD and VA stakeholders
(Product)
- Presentations to DoD and VA stakeholders (Product)
- Presentations at scientific meetings (Product)

Appendix B – Participant Recruitment, Enrollment, and Retention (through 9/20/2012)

Status	All	EW	CW	NoW
Randomized	1,438	577	572	289
Baseline				
Completed	1,275 (89%)	503 (87%)	502 (88%)	270 (93%)
Not completed	163 (11%)	74 (13%)	70 (12%)	19 (7%)
Writing Sessions				
0 Sessions	144 (14%)	82 (16%)	62 (12%)	
1-3 Sessions	308 (31%)	166 (33%)	142 (28%)	
4 Sessions	553 (55%)	255 (51%)	298 (59%)	
3-month Follow-up				
Completed	957 (84%)	355 (80%)	376 (84%)	226 (91%)
Not completed	184 (16%)	87 (20%)	74 (16%)	23 (9%)
Pending	134	61	52	21
6-month Follow-up				
Completed	655 (80%)	244 (78%)	258 (79%)	153 (86%)
Not completed	160 (20%)	69 (22%)	67 (21%)	24 (14%)
Pending	460	190	177	93

Appendix C – Preliminary Baseline Descriptive Statistics (through 8/7/2012)

Variable	n	%	Variable	n	%
Gender			VA Status		
Male	764	61.07	VA User	808	64.59
Female	487	38.93	VA Non-user	443	35.41
Race			Marital Status		
White	633	66.14	Married	772	61.46
Nonwhite	324	33.86	Not Married	484	38.54
Employment Status			Student Status		
Employed	917	73.01	Student	449	35.75
Not Employed	339	26.99	Not Student	807	64.25
Income			Education		
0-20,000	197	17.22	High School/GED	105	8.36
20,001-40,000	277	24.21	Some College	519	41.32
40,001-60,000	248	21.68	College or More	604	48.09
60,000+	422	36.89	Other	28	2.23
Service Branch			Bing Drinking (past month)		
Air Force	194	15.47	Yes	536	43.44
Army	721	57.50	No	698	56.56
Marine Corps	130	10.37			
Navy	207	16.51			
Other	2	0.16			
PCL PTSD Screen			TBI Screen		
PTSD	420	33.87	TBI	103	8.20
No PTSD	820	66.13	No TBI	1153	91.80
Variable	Mean	SD	Variable	Mean	SD
Age (years)	36.91	9.80	Time Since Deployment (years)	5.30	2.47
PDS Lifetime Trauma History	3.84	2.19	DRRI Combat Exposure	4.87	4.01
Satisfaction with Life Scale	20.88	7.62	BSI-18 Global Severity	1.02	0.74
BSI-Anxiety	1.07	0.90	BSI-Depression	1.19	0.91
BSI-Somatization	0.80	0.75	BSI Hostility	1.15	0.79
Pennebaker Inventory of Limbic Languidness	39.44	29.03	PCL Total PTSD Severity	39.58	16.19
DRRI Social Support	53.22	10.64	M2C-Q Reintegration	1.40	0.90